IN THE U.S PATENT AND TRADEMARK OFFICE

Applicant Name: Samuel C. Evans
Appl. No: 10/814,450 Filed on: March 31, 2004
Art unit: 1616 Examiner: Sharmila S. Gollamudi

FOR: SYNERGISTIC TOPICALLY APPLIED PERSONAL HYGIENE PRODUCT

DECLARATION

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I, SAMUEL C. EVANS, residing at 457, Arnold Street, NE, ATLANTA, GA 30308, the Inventor and the Applicant in respect of the above-identified US Patent Application do hereby declare as follows:

1. I have filed the US Patent Application numbered 10/814,450 on March 31, 2004, claiming priority from Indian Patent Application No. 550/DEL/2003 dated March 31, 2003.

2. The currently amended claim 1 of the above-identified Patent Application is directed towards a synergistic topically applied personal hygiene composition comprising 8 to 12 % by wt. of Povidine-Iodine complex, 0.5 to 1.0 % by wt. of potassium iodide, 1 to 10 % by wt. of phosphate, 5 to 15 % by wt. chlorhexidine acetate, 5 to 20 % by wt. of alcohol, 1 to 5 % by wt. of citric acid and the remaining being pharmaceutically acceptable excipients, wherein said composition disinfects or inhibits or restrains or controls or reduces the potential transmission of *E. coli*, *Staphylococcus aureus*, *Hemolytic streptococcus*, *Pseudomonos aeruginosa*, *Candida albicans*, *Herpes Simplx virus II*, *Neisseria gonorrhea*, *Trichomanas vaginalis*, Hepatitis B virus, Hepatitis A virus, *Chlamydia trachomatis*, *Ureaplasma urealyticum*, *Treponema pallidum* or HIV.

3. I have reviewed the Office Action issued on December 20, 2006 in respect of US patent application number 10/814,450. The Examiner has raised the objection that the claims

of the present invention are lacking inventive step in view of Sackler et al., taken along with Thompson, Davis et al. and Mody et al.

4. It is respectfully submitted that the composition of the present invention is a synergistic composition as is demonstrated in the enclosed table.

5. That even by combining the teachings of the cited documents, it is not possible to arrive at the synergistic composition being claimed in claim 1.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further declare that these statements were made with the knowledge that such willful statement may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

BY: Samuel C. Evans

Inventor and Applicant

Dated this 6-18-2007

Table establishing synergistic effect of the composition

S No.	Microbe	Chemical	Original			1/10 dilution			1/20 dilution		
			5'	15'	30'	5'	15'	30'	5'	15'	30'
1.	E. coli	Povidone iodine complex	Nil	Nil	95.53	Nil	Nil	92.65	Nil	Nil	90.96
2.		Potassium iodide	64.99	84.29	97.62	55.66	77.79	96.82	46.87	56.17	81.94
3.		Calcium phosphate	66.77	86.77	98.21	67.87	84.56	97.22	49.17	69.75	92.38
4.		Chlorhexidine Gluconate	79.54	89.62	100	88.01	89.28	100	79.25	89.15	99.62
5.		Genvia	100	100	Not tested	100	100	Not tested	100	100	Not tested
6.	Candida	Povidone iodine complex	Not tested	30.76	57.69	Not tested	19.23	38.46	Not tested	57.69	21.75
7.		Potassium iodide	Not tested	71.15	76.53	Not tested	55.76	67.15	Not tested	51.92	46.15
8.		Calcium phosphate	Not tested	38.46	71.15	Not tested	17.30	28.84	Not tested	57.69	55.76
9.		Chlorhexidine Gluconate	Not tested	78.84	88.07	Not tested	73.07	82.30	Not tested	63.46	76.54
10.		Genvia	Not tested	99.01	100	Not tested	98.88	100	Not tested	98.84	100

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1. I have filed the US Patent Application numbered 10/814,450 on March 31, 2004, claiming priority from Indian Patent Application No. 550/DEL/2003 dated March 31, 2003.

2. Claim 1 of the above-identified Patent Application is directed towards a synergistic topically applied personal hygiene composition comprising 8 to 12 % by wt. of Povidine-Iodine complex, 0.5 to 1.0 % by wt. of potassium iodide, 1 to 10 % by wt. of phosphate, 5 to 15 % by wt. chlorhexidine acetate, 5 to 20 % by wt. of alcohol, 1 to 5 % by wt. of citric acid and the remaining being pharmaceutically acceptable excipients which provides disinfection against commonly known pathogens and prevents transmission of most of the sexually transmitted diseases.

3. I have reviewed the Office Action issued on December 20, 2006 in respect of US patent application number 10/814,450. The Examiner has stated that "*the specification, while being enabling for providing disinfection against commonly known pathogens, does not reasonably provide enablement for preventing the transmission of most sexually transmitted diseases*". More specifically, the Examiner indicates that "*the guidance provided by the specification does not reasonably demonstrate that the instant composition prevents the transmission of STDs*". The Examiner indicates that "*the term "prevention" is an absolute definition, which means to stop from occurring and it is not just the reduction of the potential risk of transmitting (for instance by reducing friction that causes cuts); thus the term requires a higher standard for enablement than a term such as "reducing"*".

4. In view of the above objection, the claim have been amended so as to indicate that the composition of the present invention "**disinfects or inhibits or restrains or controls or reduces the potential transmission of**" *E. coli, Staphylococcus aureus, Hemolytic*

streptococcus, *Pseudomonos aeruginosa*, *Candida albicans*, *Herpes Simplx virus II*, *Neisseria gonorrhea*, *Trichomanas vaginalis*, Hepatitis B virus, Hepatitis A virus, *Chlamydia trachomatis*, *Ureaplasma urealyticum*, *Treponema pallidum* or HIV. The language which is now adopted in claim 1 is based on the Examiner's own suggestion contained in paragraph 2 of page 3.

5. In addition to the above amendment, I would like to submit that the tests have been performed at a number of neutral, reputed, institutes such as Institute of Dermatology, Chinese Academy of Medical Science, National Center for STD and Leprosy Control in accordance with the relevant federal laws, regulations and requirements stipulated in Decree of National Health and Anti-epidemic Infection issued by Ministry of Public Health of the People's Republic of China. All the certificates that have been issued by the Institutes are annexed herewith as documentary evidence of the working of the claimed composition.

More particularly, the following tests were conducted prior to the date of filing of the application on the composition of the present invention, which is provided the trade name of Genvia®:

(a) Quality Test & Inspect Report: Genvia® Topical Composition's Effectiveness of Destroying HBsAg - This test was conducted by Nanjing City Sanitation and Anti-Epidemic infection Department on December 13, 1999 – See Annexure A for further details.

(b) Report on Quality Test: Genvia® Topical Composition's Texicity Test and Evaluation - This test was conducted by Analytic and test Center, Nanjing Railway Medical College of China on January 13, 2000 – See Annexure B for further details.

(c) Genvia® Topical Composition's Quality Test & Inspection Report - This test was conducted by Nanjing City Sanitation and Anti-Epidemic infection Department on August 13, 1999 – See Annexure C for further details.

(d) Genvia® Topical Composition's Inhibition Effect on Bacteria Growth - This test was conducted by Nanjing City Sanitation and Anti-Epidemic infection Department on August 18, 1999 – See Annexure D for further details.

(e) Quantitative Measurement of Sporicidal Effect of Genvia® Topical Composition - This test was conducted by Nanjing City Sanitation and Anti-Epidemic infection Department on August 18, 1999 – See Annexure E for further details.

(f) Stability Test of Genvia® Topical Composition Determined Using Bacillus subtillis - This test was conducted by Nanjing City Sanitation and Anti-Epidemic infection Department on August 18, 1999 – See Annexure F for further details

(g) Stability Test of Genvia® Topical Composition Determined Using Escherichia Coli and Staphylococcus aureus - This test was conducted by Nanjing City Sanitation and Anti-Epidemic infection Department on August 18, 1999 – See Annexure G for further details.

(h) Quantitative Measurement of Effect of Killing Yeast of Genvia® Topical Composition – This test was conducted by Nanjing City Sanitation and Anti-Epidemic infection Department on August 18, 1999 – See Annexure H for further details.

(i) The Effectiveness of Genvia® Topical Composition on Neisseria Gonococcus- This test was conducted by Clinical Laboratory Department, Gu-Lou Hospital, Affiliated to Medical College of Nanjing University On December 31, 1999 – See Annexure I for complete details

(j) Effects of Bactericide Test of Genvia® Topical Composition on Neisseria Gonococcus With Gonococcal Infection in Men (in-vitro study) – This test was conducted by National Center for STD and Leprosy Control, Institute of Dermatology, Chinese Academy of Medical Science on August 12, 1999– See Annexure Q for complete details.

(k) The Effectiveness of Genvia® Topical Composition on Vaginal Trichomonas - This test was conducted by Clinical Laboratory Department, Gu-Lou Hospital, Affiliated to Medical College of Nanjing University On December 30, 1999 – See Annexure N for complete details.

(l) The Effectiveness of Genvia® Topical Composition on Damaging HBsAg - This test was conducted by Clinical Laboratory Department, Gu-Lou Hospital, Affiliated to Medical College of Nanjing University On December 29, 1999 – See Annexure L for complete details.

(m) The Effectiveness of Genvia® Topical Composition on Damaging HAAg - This test was conducted by Clinical Laboratory Department, Gu-Lou Hospital, Affiliated to Medical College of Nanjing University On Jnauary 6, 2000 – See Annexure M for complete details.

(n) The Effectiveness of Genvia® Topical Composition on Killing Human Sperm - This test was conducted by Clinical Laboratory Department, Gu-Lou Hospital, Affiliated to Medical College of Nanjing University On December 27, 1999 – See Annexure N for complete details.

(o) Activity of Genvia® Topical Composition to Reverse Transcriptase of HIV-1 - This test was conducted by National Center for STD and Leprosy Control, Institute of Dermatology, Chinese Academy of Medical Science on 2000/03/08 – See Annexure P for complete details.

(p) Activity of Genvia® Topical Composition for In vitro bactericidal effects on Neisseria Gonorrhoeae - This test was conducted by National Center for STD and Leprosy Control, Institute of Dermatology, Chinese Academy of Medical Science on August 26, 1999– See Annexure Q for complete details.

(q) Activity of Genvia® Topical Composition for In vitro bactericidal effects on Mycoplasma - This test was conducted by National Center for STD and Leprosy Control, Institute of Dermatology, Chinese Academy of Medical Science on August 26, 1999 – See Annexure R for complete details.

(r) Effect of Immobilization test of Genvia® Topical Composition on Treponema Pallidum in vitro- This test was conducted by National Center for STD and Leprosy Control, Institute of Dermatology, Chinese Academy of Medical Science on August 4, 1999 – See Annexure S for complete details.

(s) In vitro Bactericidal Effects of Genvia® Topical Composition on Chlamydia Trachomatis - This test was conducted by National Center for STD and Leprosy Control, Institute of Dermatology, Chinese Academy of Medical Science on August 26, 1999 – See Annexure T for complete details.

(t) In vitro bactericidal effects of Genvia® Topical Composition on Trichomonas Vaginalis - This test was conducted by National Center for STD and Leprosy Control, Institute of Dermatology, Chinese Academy of Medical Science on January 26, 2000 – See Annexure U for complete details.

(u) In vitro inhibition of HIV Reverse Transcriptase by Genvia® Topical Composition – This test was conducted by National Center for STD and Leprosy Control, Institute of Dermatology, Chinese Academy of Medical Science on January 31, 2000 – See Annexure V for complete details.

(v) In vitro Inactive Effect of Genvia® Topical Composition on Herpes Simplex Virus Type 2 – This test was conducted by National Center for STD and Leprosy Control, Institute of Dermatology, Chinese Academy of Medical Science On August 19, 1999 – See Annexure W for complete details.

As it can be noticed from the annexed certificates, a number of in-vitro experiments were conducted in order to test the working of the claimed composition. Annexure O provides a short listed list of volunteer patients.

In view of the above, it is respectfully submitted that the working of the claimed composition has been tested under in-vitro conditions also.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further declare that these statements were made with the knowledge that such willful statement may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

BY: Samuel C. Evans

Inventor and Applicant

Dated this 6-18-2007

Annexure A

Quality Test & Inspect Report: Genvia® Topical Composition's Effectiveness of Destroying HBsAg

Test conducted by:
Nanjing City Sanitation and Anti-Epidemic Infection Department
On December 13, 1999

(98)量认(苏)字(Z0131)号

质量检测报告书

宁卫防(消)检字第 99087号

共 4页 第1页

样品名称：表面消毒剂

受检单位：艾文斯—卡特(南京)有限公司

南京市卫生防疫站

一九九九 年 十二 月 十三 日

质检报告书说明

一、对检测结果如有异议者，请于收到报告之日起15天内向本站提出。

二、委托检测，系委托者自带检品送检，本报告书仅对送检检品的检测结果负责。

三、监督检测，系按有关法规进行的监督性检测。

四、鉴定检测，系对新产品、新工艺、新资源的有关质量检测。

五、仲裁检测，系按争议双方协商情况或有关主管部门抽封样、其实物质量检测结果作为上级部门判定质量的依据。

六、本站仅对确认后加盖本站鲜公章的复制件负责。

南京市卫生防疫站地址 紫竹林2号　　邮编：210003

电话号码（直拨）3426233　3424903　3427298转304

检 验 报 告

宁卫防(消)检字第(990870)号第3页

样品编号 9912088041

样品名称 表面消毒剂	检测类别 委托
规格批号 9912003	商 标 无
样品数量 1瓶	包装情况 玻瓶
生产单位 艾文斯—卡特公司	采样地点 自送样
受检单位 艾文斯—卡特公司	收样日期 1999.12.6

检测依据 << 消毒与灭菌效果的评价方法与标准 >> GB15981-1995

检测结果:

表面消毒剂对HBsAg的破坏作用

消毒剂浓度	不同作用时间(分)S/N值及(OD)值 15	30	60
原液	0.96 (0.052)	0.33 (0.018)	0.24 (0.013)

注: HBsAg阳性对照OD值为1.656, HBsAg阴性对照OD值为0.054, S/N值<2.1为破坏合格.

本报告仅对送检样品负责

编制: 夏理评 审核: 贾力敏 签发: 检测机构检验章:

99年12月13日

检测环境条件

环境温度：25℃

相对湿度：70%

主要检测用仪器

编　　号	名　　称	型　　号	
16317	酶标仪	Reader230S	
16318	洗板机	Washer430	

检测说明

Quality Test & Inspection Report

Nanjing Public Health (Disinfectant) Testing No. 990870

(Four pages in total)
Page 1

Client: EVANS-CARTER INTERNATIONAL (NANJING) CO. LTD

Nanjing City Sanitation & Anti-Epidemic Infection Department

December 13 1999

Instruction of the Quality Test Report

1. Should you have any dispute on the result(s), please contact our department within 15 days after receiving this report
2. The report is only responsible for the sample sent by client.
3. Supervisory tests are conducted under relevant law and regulations.
4. Appraisal tests are the inspections on new product, techniques and resources.
5. Testing results are the basis upon which government makes the judgement.
6. Our department is only responsible for the copies with original stamps.

If you have any question, please contact us at:

Address: #2 Zi-Zhu-Lin Nanjing, P. R. China 210003

Tel: 342-6233 342-4903 342-7298 Ext. 304

Sample's Code: 9912088041

Sample's Name: Genvia Topical Disinfectant	Type of Inspection: clientage
Batch Code: 9912003	Trademark: Genvia
Quantity of Sample: one bottle, 250ml	Package: Glass Bottle
Manufacturer: Evans-Carter International, Inc.	Place of Sampling: sent by client
Client: Evans-Carter International, Inc.	Received Date: Dec. 6, 1999

Test Method:

The assay is conducted under the Protocol and Evaluation Standard of Ministry of Public Health of China for Disinfectant Products **GB15981-1995**

Test Result:

Genvia topical disinfectant's effectiveness of destroying HBsAg

Dilution of Genvia	S/N value and OD value after different reaction time		
	15	30	60
Original solution	S/N: 0.96 OD: 0.052	S/N: 0.33 OD: 0.018	S/N: 0.24 OD: 0.013

Notice: HBsAg The OD reading of Positive Reference is 1.656, HBsAg Negative Reference OD value is 0.054. If calculated S/N value of sampleis $\leqslant 2.1$, it indicates the HBsAg destroying effect of Genvia meets the standard.

This report is only responsible to the sample received.

Compiled by: Xia Li-Pin
Checked by: Jia Li-Min
Signed by: Duan Chang-Lin

Stamp of Testing Government Agency
December 13, 1999

Temperature: 25 degree centigrade

Relative Humidity: 70%

Test Machine(s)

Code	Name	Specifications
16317	ELISA	ELISA230S
16318	Micro-titer Washer	Washer430

Annexure B

Report on Quality Test: Genvia® Topical Composition's Texicity Test and Evaluation

Test conducted by:
Analytic and test Center
Nanjing Railway Medical College of China
On January 13, 2000

CMA

(96)量认(苏)字(Z0311)号

南京铁道医学院
分析检测中心
Analytic and Test Centre
Nanjing Railway Medical College

质量检测报告书

REPORT ON QUALITY TEST

（毒）检字第 56 号

检品名称 精维表面抗菌剂

送检单位 南京市卫生防疫站

被检单位 艾文斯一卡特国际（南京）公司

2000 年 1 月 13 日

质 检 报 告 书 说 明

1 对检测结果有异议者，请于收到报告之日起 15 天内向本中心提出。

2 委托检测系被检单位自带检品送检，本报告书仅对送检样品的检测结果负责。

3 鉴定检测系对新产品、新工艺、新资源的有关质量检测。

4 监督检测系按有关法规进行的监督性检测。

5 仲裁检测系按争议双方协商情况或有关主管部门抽封样，其实物质量检测结果作为上级有关部门判断质量的依据。

6 本中心仅对确认后加盖本中心公章的复制件负责。

南京铁道医学院分析检测中心

评 价 报 告

(毒)检字第 56 号 共 6 页 第 3 页

检测报告编号 99122701020032

样品名称：精维表面抗菌剂　　样品性状：棕色液体

生产单位：艾文斯一卡特国际（南京） 公司　　检验类别：监督检验

地　　址：　　接样日期：1999－12－27

委托单位：南京市卫生防疫站　　试验目的：产品报批

试验项目：经口急毒、皮肤刺激　　样品批号：991122

样品包装、数量：250ml 玻璃瓶装×1

检测和评价依据：卫生部《消毒技术规范》中“消毒剂毒理试验的程序和方法”

检测结论

1. 小鼠经口毒性试验：

精维表面抗菌剂小鼠经口半数致死量(LD_{50})大于 5000mg/Kg 体重，属于实际无毒物质。

2. 家兔一次皮肤刺激试验：

家兔各时间的皮肤刺激反应积分值（刺激指数）为 0.25，精维表面抗菌剂对皮肤无刺激性。

编 制 李纯德

审 校 [illegible]

签 发 [illegible]

检 验 章

2000年1月13日

南京铁道医学院分析检测中心
检　测　报　告

(毒)检字第 56 号 共 6 页 第 4 页
检测报告编号 9912270101032

样品名称：精维表面抗菌剂　　样品性状：棕色液体
生产单位：艾文斯一卡特国际（南京） 公司　　检验类别：监督检验
地　　址：　　接样日期：1999－12－27
委托单位：南京市卫生防疫站　　试验目的：产品报批
试验项目：经口急毒、皮肤刺激　　样品批号：991122
样品包装、数量：250ml 玻璃瓶装×1
检测和评价依据：卫生部《消毒技术规范》中“消毒剂毒理试验的程序和方法”

检测结果

小鼠经口急性毒性试验

实验动物：昆明种小鼠(动物合格证号：苏动质 97002)
实验方法：按照“消毒剂毒理试验的程序和方法”进行。取体重 18－22 克的健康昆明种小鼠 100 只，随机分成 5 组，雌雄各半。将精维表面抗菌剂原液配成 5000、4545、4132、3757、3415mg/Kg 体重五个剂量组。经口灌胃后观察两周。
实验结果：至观察期结束各组动物均无死亡。所以精维表面抗菌剂小鼠经口半数致死量(LD_{50})大于 5000mg/Kg 体重。根据消毒剂毒性分级标准，精维表面抗菌剂属于实际无毒物质。

表 1　　小鼠死亡数及其 LD_{50} 值

剂量 (mg/Kg)	死亡动物数/实验动物数 雄	雌	LD_{50} 值及其 95%可信限(mg/Kg) 雄	雌
3415	0/10	0/10		
3757	0/10	0/10		
4132	0/10	0/10	均大于 5000	
4545	0/10	0/10		
5000	0/10	0/10		

编制 李纯
审校 洪伟君
签发

检验章
2000 年 1 月 13 日

检测结果

兔皮肤刺激试验

实验动物：健康白兔。

实验方法：取健康白兔 4 只，体重 1.8-2.0Kg。脊柱两侧剪毛 2.5cm×2.5cm 各一块。试验时将 0.2ml 精维表面抗菌剂涂在 一侧皮肤上，另一侧皮肤涂等量蒸馏水作为对照。用一层油纸覆盖，绷带固定。6 小时后取下纱布，用温水洗净敷贴部位皮肤。于取除受试物后 1、24 和 48 小时，观察皮肤局部反应。

实验结果：见表 2

表 2 精维表面抗菌剂皮肤刺激试验皮肤反应积分汇总

	兔号																刺激反应积分					
	1				2				3				4									
时间(h)	样品红斑	样品水肿	对照红斑	对照水肿	样品红斑	样品水肿	对照红斑	对照水肿	样品红斑	样品水肿	对照红斑	对照水肿	样品红斑	样品水肿	对照红斑	对照水肿	样品红斑	样品水肿	样品总分	对照红斑	对照水肿	对照总分
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

总积分	1
皮肤刺激指数	0.25

编制 李纯德

审校 张伟君

签发 [illegible]

检 验 章

2000 年 1 月 13 日

检验说明：

实验动物：健康小鼠
健康白兔

主要检验用仪器

编　号	名　称	型　号	备　注
01	电子秤	tcs-5000-A	

检验环境条件：

温　度　25 ±2℃
湿　度　75 ±5%

Analytic and Test Center

Nanjing Railway Medical College of China

PRODUCT QUALITY REPORT

(Toxicity) Test & Evaluation #56

Product's Name: Genvia Topical Disinfectant

Sent by: Nanjing City Sanitation & Anti-epidemic Department

Test Applicant: Evans-Carter International (Nanjing) Co. Ltd.

January 13, 2000

Instruction of the Quality Test Report

1. Should you have any dispute on the result(s), please contact our department within 15 days after receiving this report

2. The report is only responsible for the sample sent by client.

3. All of the tests are conducted according to relevant law and regulations.

4. Appraisal tests are the inspections on new product, techniques and resources.

5. Testing results are the basis upon which government makes its appraisal decision.

6. Our Center is only responsible for the copies with original stamps.

REPORT ON QUALITY TEST

(Disinfectant) Test & Evaluation #56
Test Series #9912270102032

Product's Name: Genvia Topical Disinfectant	Sample Color: Brown liquid
Manufacturer: Evans-Carter International (Nanjing) Co. Ltd.	Test Category: Inspection, Test, Evaluation and appraisal
Address:	Sample Receive: 1999-12-27
Sample sent by: Nanjing City Sanitation & Anti-epidemic Department	Test Purpose: Product Approval
Test Objects: 1. Oral-feeding/acute test 2. Skin stimulation and irritation	Sample Batch No.: 991122
Sample Packed: 250ml × one bottle	
Assay Method is based upon "Protocol of Toxicity Test and Evaluation of Disinfectant Product" issued by Ministry of Public Health of China	

Test Conclusion:

1). Assay of mice orally feeding:
LD_{50} of Genvia topical disinfectant is larger than 5000mg/Kg of body weight. It actually is belong to the material that has no toxicity.

2). Assay of skin irritation on rabbit (single dose stimulation)
At each observing and recorded time, rabbit skin accumulation index of stimulation reaction is 0.25. Genvia topical disinfectant has no irritation effect on skin.

Report written by: Li Chun-De
Edited by: Tan Wei-Jun
Supervisor: Tang Meng

Seal
January 13, 2000

(Disinfectant) Test & Evaluation #56
Test Series #9912270102032

Product's Name: Genvia Topical Disinfectant	Sample Color: Brown liquid
Manufacturer: Evans-Carter International (Nanjing) Co. Ltd.	Test Category: Inspection, Test, Evaluation and Appraisal
Address:	Sample Receive: 1999-12-27
Sample sent by: Nanjing City Sanitation & Anti-epidemic Department	Test Purpose: Product Approval
Test Objects: 1. Oral-feeding/acute test 2. Skin stimulation and irritation	Sample Batch No.: 991122
Sample Packed: 250ml × one bottle	
Assay Method is based upon "Protocol of Toxicity Test and Evaluation of Disinfectant Product" issued by Ministry of Public Health of China	

Test Result:

Assay of Toxicity by Oral Feeding on Mice

Testing Animal: Kun Ming mice (Test animal certified No.: Jiangsu Animal Quality 97002)

Assay Method: According to "Protocol of Toxicity Test and Evaluation of Disinfectant Product" issued by Ministry of Public Health of China. Select 100 healthy Kun Ming mice (each weighs 18-20 grams), female/male are equal in number, randomly divided into five (5) groups. Prepare original solution of Genvia topical disinfectant into five (5) dosage groups of 5,000mg/Kg, 4,545mg/Kg, 4,132mg/Kg, 3,757mg/Kg, 3,415mg/Kg of body weight. Orally fed two weeks and observe.

Test Result: From day one to the completion of the test, there is no single animal in any dosage group died.

Conclusion: LD_{50} of Genvia topical disinfectant through orally feeding is larger than 5,000mg/Kg per body weight. According to grade standard of disinfectant issued by Ministry of Public Health of China, Genvia topical disinfectant belongs to the material of having no actual toxicity.

	Male	Female	Male	Female
3,415	0/10	0/10		
3,757	0/10	0/10		
4,132	0/10	0/10	Both are larger than 5,000	
4,545	0/10	0/10		
5,000	0/10	0/10		

Report written by: Li Chun-De

Edited by: Tan Wei-Jun

Supervisor: Tang Meng

Seal

January 13, 2000

Test Result

Skin Stimulation Test on Rabbit

Testing Animal: Healthy Rabbits

Assay Method: Use four (4) healthy rabbits, body weight is 1.8-2.0Kg. Cut hair along both sides of spine, 2.5cm × 2.5cm on each side. Apply 0.2ml original liquid of Genvia on the surface on one side. On the other side, add 0.2ml of distilled water as reference. Cover both surface areas by using oil paper and use bandage to fix to ensure the continuing contacting. Uncover the bandage after six (6) hours. Use warm water to clean both surface areas. Observe and record local skin of at 1, 24 and 48 hours.

Test Result: See table-2

Table-2: Accumulated Skin Reaction Index of Genvia Topical Disinfectant

	Rabbit																Stimulation Index			Accumulation		
	1				2				3				4									
Time (h)	Sample		Distilled Water Ref.		Sample		Distilled Water Ref.		Sample		Distilled Water Ref.		Sample		Distilled Water Ref.		Sample		Total	Distilled Water Ref.		
	SKIN REASH	LOCAL SKIN EDEMA	SKIN REASH	LOCAL SKIN EDEMA	SKIN REASH	LOCAL SKIN EDEMA	SKIN REASH	LOCAL SKIN EDEMA	SKIN REASH	LOCAL SKIN EDEMA	SKIN REASH	LOCAL SKIN EDEMA	SKIN REASH	LOCAL SKIN EDEMA	SKIN REASH	LOCAL SKIN EDEMA	SKIN REASH	LOCAL SKIN EDEMA	Total	SKIN REASH	LOCAL SKIN EDEMA	
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Report written by: Li Chun-De
Edited by: Tan Wei-Jun
Supervisor: Tang Meng

Seal

January 13, 2000

Notice:
Testing Animal: Healthy Mice
Healthy Rabbit

Major Testing Instrument(s):

Series	Name	Specifications	Memo
01	Electronic Scale	tcs-5000-A	

Testing Condition:
Temperature: 25 ± 2 degree centigrade
Moisture: 75 ± 5 %

Annexure C

Genvia® Topical Composition's Quality Test & Inspection Report

Test conducted by:
Nanjing City Sanitation and Anti-Epidemic Infection Department
On August 13, 1999

(98)量认(苏)字(Z0131)号

质量检测报告书

宁卫防(消)检字第990573号

共7页 第1页

样品名称：精维表面抗菌剂

受检单位：艾文斯--卡特国际(南京)有限公司

南京市卫生防疫站

一九九九年八月十三日

License # (98) Quantitative (Jiangsu): Z0131

Quality Test & Inspection Report

Nanjing Public Health (Disinfectant) Testing No. 990573

Product Name: Genvia Topical Disinfectant

Client: EVANS-CARTER INTERNATIONAL (NANJING) CO. LTD

Nanjing City Sanitation & Anti-Epidemic Infection Department

August 13 1999

质检报告书说明

一、对检测结果如有异议者，请于收到报告之日起15天内向本站提出。

二、委托检测，系委托者自带检品送检，本报告书仅对送检检品的检测结果负责。

三、监督检测，系按有关法规进行的监督性检测。

四、鉴定检测，系对新产品、新工艺、新资源的有关质量检测。

五、仲裁检测，系按争议双方协商情况或有关主管部门抽封样、其实物质量检测结果作为上级部门判定质量的依据。

六、本站仅对确认后加盖本站鲜公章的复制件负责。

南京市卫生防疫站地址 紫竹林2号　　邮编:210003

电话号码（直拨）3426233　3424903　3427298转304

1. Should you have any dispute on the result(s), please contact our department within 15 days after receiving this report
2. The report is only responsible for the sample sent by client.
3. All of the tests are conducted according to relevant law and regulations.
4. Appraisal tests are the inspections on new product, techniques and resources.
5. Testing results are the basis upon which government makes decision.
6. Our department is only responsible for the copies with original stamps.

If you have any question, please contact us at:

Address: #2 Zi-Zhu-Lin Nanjing, P. R. China 210003

Tel: 342-6233 342-4903 342-7298 Ext. 304

Annexure D

Genvia® Topical Composition's Inhibition Effect on Bacteria Growth

Test conducted by:
Nanjing City Sanitation and Anti-Epidemic Infection Department
On August 18, 1999

检 验 报 告

宁卫防(消)检字第(990579)号第3页

样品编号 9907264701

样品名称	表面消毒剂	检测类别	委托
规格批号	990720	商 标	精维
样品数量	2瓶	包装情况	原玻瓶装包装完好
生产单位	艾文斯一卡特国际有限公司	采样地点	自送样
受检单位	艾文斯一卡特国际有限公司	收样日期	1999.7.26

检测依据 << 消毒与灭菌效果的评价方法与标准 >> GB15981-1995

检测结果:

中和剂选择性试验

一. 材料: 1) 试验菌株: 大肠杆菌8099
2) 中和剂: 含1.0%$Na_2S_2O_3$的PBS液 (PH7.2)

二. 方法: 按照<< 消毒与灭菌效果的评价方法与标准 >> GB15981-1995作八组化学中和法, 作用时间为2分钟, 消毒剂浓度为原液.

三. 结果:

消毒剂对细菌繁殖体的中和剂试验结果

组别	试验液组成	活菌计数 (cfu/mL)
1	消毒剂+菌液	19
2	(消毒剂+菌液)+中和剂	1.40×10^2
3	中和剂+菌液	1.62×10^6
4	(消毒剂+中和剂)+菌液	1.62×10^6
5	PBS +菌液	1.62×10^6
6	PBS液	0
7	中和剂	0
8	未接种细菌的培养基	0

试验结果表明: 含1.0%$Na_2S_2O_3$的PBS液 (PH=7.2), 可以中止该消毒剂的残留毒性, 对培养基无影响, 对试验菌无毒性, 故判其为该消毒剂杀细菌繁殖体的中和剂.

本报告仅对送检样品负责

编制: 审核: 签发: 检测机构检验章

99年10月27日

Sample's Code: 9907264701 Sample's Name: Genvia Topical Disinfectant	Type of Inspection: clientage
Batch Code: 990720	Trademark: Genvia
Quantity of Sample: Two bottles, 250ml	Package: Glass Bottle
Manufacturer: Evans-Carter International, Inc.	Place of Sampling: sent by client
Client: Evans-Carter International, Inc.	Received Date: July 26, 1999

Neutralizer Selection Test

Material:

1). Testing bacteria: E. Coli 8099

2). PBS solution contains 1.0% Na_2O_3 (pH7.2)

The assay is conducted under the Protocol and Evaluation Standard of Ministry of Public Health of China for Disinfectant Products **GB15981-1995.** Devide testing pathogen into eight (8) test groups. Reaction time is 2 minutes. Genvia solution used is non-diluted.

Test Result of Inhibition effect of Genvia on Bacteria Grwoing

Group	Testing ingredient composition	Bacteria count (cfu/mL)
1	Genvia + bacteria	19
2	(Genvia + bacteria) + Neutralizer	1.40×10^2

5	PBS + bacteria	1.62×10^6
6	PBS	0
7	Neutralizer	0
8	Bacteria culture without anything added	0

Conclusion: PBS solution (contains 1.0% 1.0% Na_2O_3 , pH7.2) can stop Genvia's action on inhibiting bacteria growing, and has no toxicity on bacteria alone. So, it can be used as the neutralizer for testing of inhibiting effectiveness of Genvia on bacteria culture.

This report is only responsible to the sample received.

Compiled by: Xia Li-Pin
Checked by: Jia Li-Min
Signed by: Duan Chang-Lin

Stamp of Testing Government Agency
August 18, 1999

Annexure E

Quantitative Measurement of Sporicidal Effect of Genvia® Topical Composition

Test conducted by:
Nanjing City Sanitation and Anti-Epidemic Infection Department
On August 18, 1999

检 验 报 告

宁卫防(消)检字第(990579)号第4页

样品编号 9907264701

样品名称	表面消毒剂	检测类别	委托
规格批号	990720	商　标	精维
样品数量	2瓶	包装情况	原玻瓶装包装完好
生产单位	艾文斯一卡特国际有限公司	采样地点	自送样
受检单位	艾文斯一卡特国际有限公司	收样日期	1999.7.26

检测依据　<< 消毒与灭菌效果的评价方法与标准 >> GB15981-1995

检测结果:

定量杀菌试验

一、材料: 1) 试验菌株: 枯草杆菌黑色芽胞ATCC9372
2) 中和剂: 含1.0%$Na_2S_2O_8$的PBS液 (PH7.2)
3) 消毒剂: 表面消毒剂

二、结果:

消毒剂对枯草杆菌黑色芽胞的杀灭效果

消毒剂浓度	试验菌株	不同作用时间(分)杀灭率(%) 15	30
原液	枯黑芽胞	99.94	100.00
1:10	ATCC9372	99.89	100.00
1:20		99.84	99.99

试验结果表明, 该消毒剂原液作用15分钟, 对枯黑芽胞的杀灭率为99.94%

本报告仅对送检样品负责

编制: 审核: 签发:

检测机构检验章

99年 8 月18日

Sample's Code: 9907264701 Sample's Name: Genvia Topical Disinfectant	Type of Inspection: clientage
Batch Code: 990720	Trademark: Genvia
Quantity of Sample: Two bottles, 250ml/each	Package: Glass Bottle
Manufacturer: Evans-Carter International, Inc.	Place of Sampling: sent by client
Client: Evans-Carter International, Inc.	Received Date: July 26, 1999

The assay is conducted under the Protocol and Evaluation Standard of Ministry of Public Health of China for Disinfectant Products **GB15981-1995.** Devide testing pathogen into eight (8) test groups. Reaction time is 2 minutes. Genvia solution used is non-diluted.

I). Material:

1). Testing bacteria: Endospore of Bacillus subtillis

2). PBS solution contains 1.0% Na_2O_3 (pH7.2)

3). Genvia

II). **Quantitative Measurement of Sporicidal Effect of Genvia:**

Test Result of killing effect of Genvia on bacillus subtillis:

ATCC9372	15 min.	30 min.
Original solution	99.94	100.00
1:10 Diluted	99.89	100.00
1:20 Diluted	99.84	99.99

Test results show that the killing percentage of non-diluted Genvia solution is 99.94% at 15 minutes.

This report is only responsible to the sample received.

Compiled by: Xia Li-Pin
Checked by: Jia Li-Min
Signed by: Duan Chang-Lin

Stamp of Testing Government Agency
August 18, 1999

Annexure F

Stability Test of Genvia® Topical Composition Determined Using Bacillus subtillis

Test conducted by:
Nanjing City Sanitation and Anti-Epidemic Infection Department
On August 18, 1999

检　验　报　告

宁卫防(消)检字第(990579)号第5页

样品编号 9907264701

样品名称	表面消毒剂	检测类别	委托
规格批号	990720	商　标	精维
样品数量	2瓶	包装情况	原玻瓶装包装完好
生产单位	艾文斯—卡特国际有限公司	采样地点	自送样
受检单位	艾文斯—卡特国际有限公司	收样日期	1999.7.26

检测依据

<< 消毒与灭菌效果的评价方法与标准 >> GB15981-1995

检测结果:

56℃存放14天稳定性试验

一. 材料: 1) 试验菌株: 枯草杆菌黑色芽胞ATCC9372

2) 中和剂: 含1.0%$Na_2S_2O_3$的PBS液 (PH7.2),

3) 消毒剂: 表面消毒剂

二. 结果:

消毒剂对枯黑芽胞的杀灭效果

消毒剂浓度	试验菌株	不同作用时间(分)杀灭率(%) 15	30
原液	枯黑芽胞	96.35	99.65
1:10	ATCC9372	95.33	99.53
1:20		94.28	99.38

本报告仅对送检样品负责

编制: 杜冰　　审核: 张昇英　　签发:

检测机构检验章:

1999年 8 月 18 日

Sample's Code: 9907264701 Sample's Name: Genvia Topical Disinfectant	Type of Inspection: clientage
Batch Code: 990720	Trademark: Genvia
Quantity of Sample: Two bottles, 250ml/each	Package: Glass Bottle
Manufacturer: Evans-Carter International, Inc.	Place of Sampling: sent by client
Client: Evans-Carter International, Inc.	Received Date: July 26, 1999

The assay is conducted under the Protocol and Evaluation Standard of Ministry of Public Health of China for Disinfectant Products **GB15981-1995.** Devide testing pathogen into eight (8) test groups. Reaction time is 2-minutes. Genvia solution used is non-diluted.

Stability Test of Genvia at 56° C for 14 days

Material:

1). Testing bacteria: Endospore of Bacillus subtillis

2). PBS solution contains 1.0% Na_2O_3 (pH7.2)

3). Genvia

Genvia Dilution	Spores of Bacillus subtillis ATCC9372	Killing % At different time (minutes) 15 min.	30 min.
Original solution		96.35	99.65
1:10 Diluted		95.33	99.53
1:20 Diluted		94.28	99.38

This report is only responsible to the sample received.

Compiled by: Xia Li-Pin
Checked by: Jia Li-Min
Signed by: Duan Chang-Lin

Stamp of Testing Government Agency
August 18, 1999

Annexure G

Stability Test of Genvia® Topical Composition Determined Using Escherichia Coli and Staphylococcus aureus

Test conducted by:
Nanjing City Sanitation and Anti-Epidemic Infection Department
On August 18, 1999

检 验 报 告

宁卫防(消)检字第(990579)号第6页

样品编号 9907264701

样品名称 表面消毒剂　　检测类别 委托

规格批号 990720　　商　标 精维

样品数量 2瓶　　包装情况 原玻瓶装包装完好

生产单位 艾文斯一卡特国际有限公司　　采样地点 自送样

受检单位 艾文斯一卡特国际有限公司　　收样日期 1999.7.26

检测依据

<< 消毒与灭菌效果的评价方法与标准 >> GB15981-1995

检测结果:

56℃存放14天稳定性试验

一. 材料: 1)试验菌株:大肠杆菌8099,金黄色葡萄球菌ATCC6538
2)中和剂:含1.0%$Na_2S_2O_3$的PBS液(PH7.2)
3)消毒剂:表面消毒剂

二. 结果:

消毒剂对细菌繁殖体的杀灭效果

消毒剂浓度	试验菌株	不同作用时间(分)杀灭率(%) 5′	15′
原液	大肠杆菌	100.00	100.00
1:10	8099	100.00	100.00
1:20		100.00	100.00
原液	金黄色葡萄球菌	100.00	100.00
1:10	ATCC6538	100.00	100.00
1:20		100.00	100.00

试验结果表明,该消毒剂经56℃存放14天后,经1:20稀释作用5分钟,对大肠杆菌杀灭率为100.00%,对金黄色葡萄球菌的杀灭率为100.00%

本报告仅对送检样品负责

编制: 审核: 签发:

检测机构检验章:

99年 8 月 18 日

Sample's Code: 9907264701 Sample's Name: Genvia Topical Disinfectant	Type of Inspection: clientage
Batch Code: 990720	Trademark: Genvia
Quantity of Sample: Two bottles, 250ml/each	Package: Glass Bottle
Manufacturer: Evans-Carter International, Inc.	Place of Sampling: sent by client
Client: Evans-Carter International, Inc.	Received Date: July 26, 1999

The assay is conducted under the Protocol and Evaluation Standard of Ministry of Public Health of China for Disinfectant Products **GB15981-1995.**

Stability Test of Genvia at 56° C for 14 days

Material:

1). Testing pathogens: Escherichia coli 8099 and Staphylococcus aureus ATCC6538

2). PBS solution contains 1.0% Na_2O_3 (pH7.2)

3). Genvia

Test Result of killing effect of Genvia on pathogens:

	5 min.	15 min.
Original solution	100.00	100.00
1:10 Diluted	100.00	100.00
1:20 Diluted	100.00	100.00

Genvia Dilution	Staphylococcus aureus ATCC6538	Killing % At different time (minutes)	
		5 min.	15 min.
Original solution		100.00	100.00
1:10 Diluted		100.00	100.00
1:20 Diluted		100.00	100.00

Conclusion: After Genvia stored at 56° C at 14 days, and diluted up to 1:20, it kills 100.00% of E. coli and staphyloccocus aureus at five (5) minutes.

This report is only responsible to the sample received.

Compiled by: Xia Li-Pin
Checked by: Jia Li-Min
Signed by: Duan Chang-Lin

Stamp of Testing Government Agency
August 18, 1999

Annexure H

Quantitative Measurement of Effect of Killing Yeast of Genvia® Topical Composition

Test conducted by:
Nanjing City Sanitation and Anti-Epidemic Infection Department
On August 18, 1999

检 验 报 告

宁卫防(消)检字第(990579)号第9页

样品编号 9907264701

样品名称	表面消毒剂	检测类别	委托
规格批号	990720	商　标	精维
样品数量	2瓶	包装情况	原玻瓶装包装完好
生产单位	艾文斯一卡特国际有限公司	采样地点	自送样
受检单位	艾文斯一卡特国际有限公司	收样日期	1999.7.26

检测依据

<< 消毒与灭菌效果的评价方法与标准 >> GB15981-1995

检测结果:

定量杀菌试验

一. 材料: 1) 试验菌株: 白色念珠菌ATCC10231
2) 中和剂: 含1.0%$Na_2S_2O_3$的PBS液 (PH7.2)
3) 消毒剂: 表面消毒剂

二. 结果:

消毒剂对真菌的杀灭效果

消毒剂浓度	试验菌株	不同作用时间(分)杀灭率(%) 15	30
原液	白色念珠菌	99.94	100.00
1:10	ATCC10231	99.91	100.00
1:20		99.83	100.00

试验结果表明,该消毒剂经1:10稀释作用15分钟,对白色念珠菌的杀灭率为99.91%

本报告仅对送检样品负责

编制: 审核: 签发: 检测机构检验章: 99年8月18日

Sample series number: 9907264701

Sample's Code: 9907264701 Sample's Name: Genvia Topical Disinfectant	Type of Inspection: clientage
Batch Code: 990720	Trademark: Genvia
Quantity of Sample: Two bottles, 250ml/each	Package: Glass Bottle
Manufacturer: Evans-Carter International, Inc.	Place of Sampling: sent by client
Client: Evans-Carter International, Inc.	Received Date: July 26, 1999

The assay is conducted under the Protocol and Evaluation Standard of Ministry of Public Health of China for Disinfectant Products **GB15981-1995.**

Quantitative Measurement of Effect of Killing Yeast of Genvia:

Material:

1). Testing pathogens: Candida albicans ATCC10231

2). PBS solution contains 1.0% Na_2O_3 (pH7.2)

3). Genvia

Genvia Dilution	Candida albicans ATCC10231	Killing % At different time (minutes)	
		15 min.	30 min.
Original solution		99.94	100.00
1:10 Diluted		99.91	100.00
1:20 Diluted		99.83	100.00

Conclusion: Upon 1:10 dilution, Genvia is able to kill 99.91% of Candida albicans at fifteen (5) minutes.

This report is only responsible to the sample received.

Compiled by: Xia Li-Pin
Checked by: Jia Li-Min
Signed by: Duan Chang-Lin

Stamp of Testing Government Agency
August 18, 1999

Annexure I

The Effectiveness of Genvia® Topical Composition on Neisseria Gonococcus

Test conducted by:
Clinical Laboratory Department,
Gu-Lou Hospital
Affiliated to Medical College of Nanjing University
On December 31, 1999

The Effectiveness of Genvia on Neisseria Gonococcus

December 31 1999

A. Method:

1. Sample: Fresh urethral secretion from three of bacteriologically diagnosed gonorrhea (male) patients.
2. Solution in Test: Genvia, Batch Code: 99.12.24
3. Procedure: Within 2 hours prior to the test, dilute Genvia with sterilized 0.9% NaCl to 1:1, 1:2, 1:5 and 1:10 solution. Smear the positive sample evenly on sterilized glass plate. Add 0.05ml Genvia of above-mentioned dilutions respectively, stop the reaction after 5 seconds, 15 seconds, 30 seconds, 1 minute, 5 minutes and 10 minutes, then Gram stain the glass plates and observe them under microscope.

B. The result is shown in the following table:

Time	Dilutions				
	N	1:1	1:2	1:5	1:10
5 seconds	+	+	+	-	-
15 seconds	+	+	+	+	+
30 seconds	+	+	+	+	+
1 minute	+	+	+	+	+
5 minutes	+	+	+	+	+
10 minutes	+	+	+	+	+

C. Analysis and Conclusion:

The symbol of "+" means that the morphology*, size of the pathogen have significant difference from those on original glass plate. The symbol of "-" shows that the scene shown under microscope has no significant

difference from that on original glass plate.

[* The morphological changes include two bodies in pair separated, the size of cytoplasm shrinks, the capsules broken and/or not intact, the Gram stain changes from G^- to G^+ and gonococcus dissolves.]

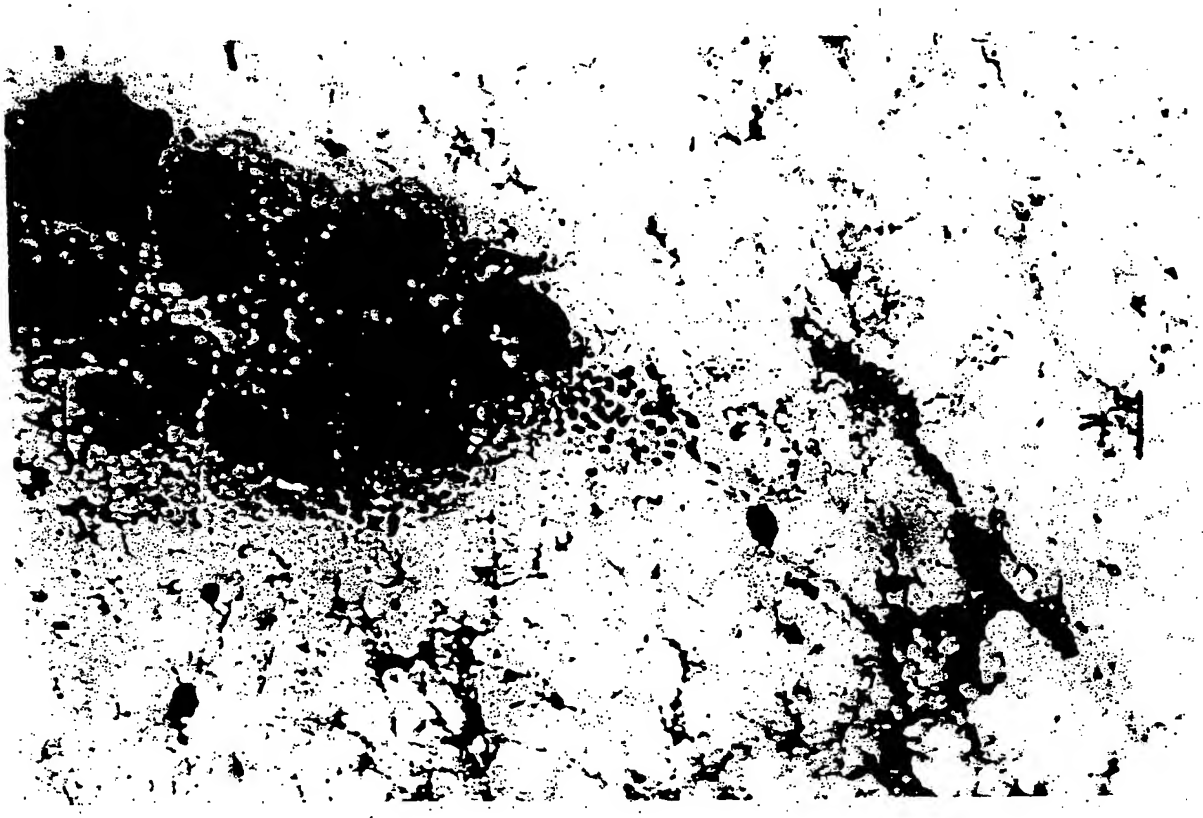
Test Conducted by: **Signature** **Seal**

孙健

[* Attached microscopic photos of gonorrhea test]

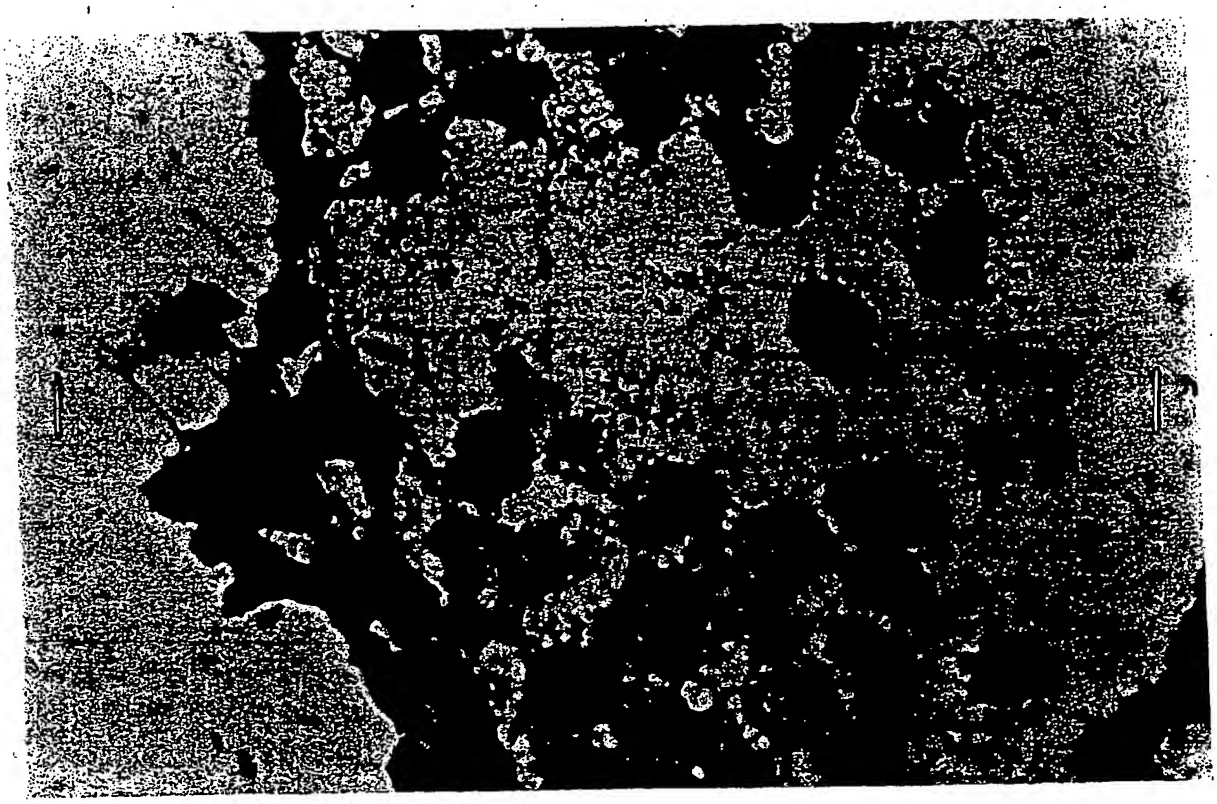
Attachment - 1 (Page 1): Microscopic photos: Bactericidal effect of Genvia on gonorrhea

Before applying Genvia: gonococcus looked healthy. They are in pair. Capsules are intact. Gram stain negative. Great in number.



Attachment - 1 (Page 2): Microscopic photos: Bactericidal effect of Genvia on gonorrhea (morphological changes)

Five (5) seconds after applying Genvia: The size of cytoplasm of gonococcus shrinks. Pairs separated. Some capsules of gonococcus broken and/or not intact. Color of Gram stain changed from G^- to G^+. Some of gonococcus is dissolving. Less in number.



Annexure J

Effects of Bactericide Test of Genvia® Topical Composition on Neisseria Gonococcus With Gonococcal Infection in Men (in-vitro study)

Test conducted by:
Institute of Dermatology, Chinese Academy of Medical Science
On August 12, 1999

分泌物中的淋球菌的杀灭效果观察

一、待检样品

Genvia™消毒液(批号:990720)，来自美国Evans－Carter International, Inc 公司。

二、材料与方法

1.性病科门诊30例男性淋病患者。

2.30例男性淋病患者分泌物涂片直接镜检阳性者进行细菌培养，用Genvia™消毒液喷在患者龟头表面部位行杀灭淋球菌，分别1分钟、5分钟后取龟头表面部位分泌物进行淋球菌培养。

三、结　果(见表)

表:用药前后体表淋球菌培养情况

时　间	例　数	
	阳　性	阴　性
用药前	30	0
用药后1分钟	2	28
用药后5分钟	0	30

四、小　结

现场使用结果表明，　Genvia™消毒液对培养阳性的30例淋病患者进行龟头表面消毒，1分钟后在龟头表面取分泌物培养，28例阴性，2例阳性，5分钟后再在龟头表面取材培养，30例均为阴性。Genvia™对淋病患者体表消毒是有效的。

检测人:沙　仲　孙厚华

中国医学科学院皮肤病研究所

1999年9月18日

GONORRHOEAE WITH GONOCOCCAL INFECTION IN MEN IN VITRO

1. Sample

GENVIA™, Evans-carter, International Inc, Batch: 990702.

2. Mater and method

(1)30 clincal patients are purulent urethrage with gonococcal infection in male pitients. The test depeds primarily on identification of N gonorrboeae at infection sites by microscopic examination of stained and culture. The Genvia™ is used on the face of balanorrhathitis. The discharge is cultured from face of balanorrhathitis at 1 minute to 5minute.

(2)Bactericide test of N. gonorrhoeae.

3. Result

The results of effects of GENVIA™ on N. gonorrhoeae are following

Effects of bactericide test of GENVIA™ ON N. gonorrboeae(Cultrer)

time	Number	
	Positive	Negative
Before using	30	0
1min	2	28
5min	0	30

4. Conclusion

The test results show that GENVIA™ had bactericide effects on H. gonorrhoeae with the case in 28 of 30 after 1min and bactericide effects on H. gonorrhoeae with the case in all of 30 at 5min. The tests compare culture of gonorrhoeae with Genvia.

Reporter: Sha Zhong, Suz HouHua

Insitute of Dermatology
Chinese Academy of Medical Science
August 12, 1999

中国医学科学院 皮肤病研究所

Annexure K

The Effectiveness of Genvia® Topical Composition on Vaginal Trichomonas

Test conducted by:
Clinical Laboratory Department,
Gu-Lou Hospital
Affiliated to Medical College of Nanjing University
On December 30, 1999

THE EFFECTIVENESS OF GENVIA ON VAGINAL TRICHOMONAS

Date: December 30 1999

A. Method and Materials:

1. **Sample**: Three samples of vaginal trichomonas are from patients diagnosed in Nanjing Women and Infant's Health Hospital. The diagnosis is further confirmed by positive observation of swimming trichomonads in a wet film of vaginal exudate. (Names are listed in the Attachment)
2. **Solution in Test**: Genvia, Batch Code: 99.12.24
3. **Procedure**: Dilute Genvia with sterilized 0.9% NaCl into 1:1, 1:2, 1:5, 1:10 and 1:50 solution. The samples are collected from vaginal exudate of positive diagnosed patient's vaginal canal, centrifuged to concentrate and checked under microscope. At room temperature, transfer the fresh sample of vaginal trichomonas onto a sterilized glass plate within 2 hours. Add 0.05ml of Genvia solution of above-mentioned dilutions respectively onto each glass plate. Observe the morphological change and mobility change after 5 seconds, 15 seconds, 30 seconds, 1 minute, 5 minutes and 10 minutes.

B. Test Result

The observations are summarized in the following table:

Time							Original Sample
5 seconds	No single of vaginal trichomonas body found	No single of vaginal trichomonas body found	Rarely bodies found, but difficult to distinguish the body	Body found. Body in number decreased No movement observed	Body found. Smaller in number Flagella's swim become less & weak	No distinguishable change Found	Body looked healthy. Flagella are moving. Good mobility Many spiral motions
15 seconds			Rarely bodies found, but difficult to distinguish the body	Much smaller in number, No movement Observed. Lose flagella	Body observed. No mobility	Weak Spiral motion found. Speed Of Flagella Movement slow down	
30 seconds			Cannot find body	No mobility, Further smaller in number. Lose flagella	Body observed. No mobility	Movement of flagella Become weak.	
1 minute			Cannot find body	Body seldom seen No mobility	Number of body decreased. No mobility.	Body found. No mobility	
5 minutes			Cannot find body	Body seldom seen No mobility	Body much less in number. No mobility.	Body found. No mobility	
10 minutes			Cannot find body	Body seldom seen No mobility	Body much less in number. No mobility,	Body found. No mobility	

A. Conclusion

The above table shows that Genvia has excellent effectiveness on killing and demobilizing vaginal trichomonas. When non-diluted Genvia or 1:1 diluted solution applied, there is no vaginal trichomonas body can be found at 5 seconds. When the dilution is 1:2, after adding it into sample for 30 seconds, no distinguishable body of vaginal trichomonas can be found. When the dilution of Genvia is 1:5, after adding it into sample for 15 seconds, the motion of vaginal trichomonas stopped completely. At 1:10 dilution for 15 seconds, vaginal trichomonads demobilized. At 1:50 dilution for one minute, vaginal trichomonads demobilized.

Test Conducted by: **Signature:** **Seal:**

Annexure L

The Effectiveness of Genvia® Topical Composition on Damaging HBsAg

Test conducted by:
Clinical Laboratory Department,
Gu-Lou Hospital
Affiliated to Medical College of Nanjing University
On December 29, 1999

THE EFFECTIVENESS OF GENVIA ON DAMAGING HBsAg

December 29 1999

A. Method and Materials:

1. Sample: 30 individual serum are collected from most recently diagnosed Hepatitis B patients (diagnosed by clinical symptoms and confirmed by clinical immunology).

2. Object in the Test:

   1). Genvia, Batch code: 99.12.24

   2). Method: ELISA

   3). Test Kit: ELISA HBsAg test kit (See attached copy), produced by Shen-Zhen Moon Bay Bioengineering Co. Ltd. Certificate Code: (93) We-Yao-Zun-Zi (Zhen-Yue) S-02; Product Code B-012; The test is conducted strictly in accordance with the instruction sheet included in the test kit.

3. Test Procedure:

   A. Numbering 30 samples of serum that have immunologically (ELISA Method) diagnosed HBsAg positive serum.

   B. Within one hour prior to the test, dilute Genvia with sterilized 0.9% NaCl in ratios of 1:1, 1:2, 1:5, 1:10. Discard the solution after two hours.

   C. Mix the Genvia solution into HBsAg positive serum, the mixing

D. Reaction temperature is 37 degree as required by test kit manufacturer. Follow each step indicated by test kit instruction sheet. Stop reaction at indicated time frames by adding $2MH_2SO_4$. Shake well and read OD at 450nm. If P/N≥2.1, it means HBsAg is still positive. If P/N<2.1, it means HBsAg is negative.

4. Average OD values of 30 samples treated by different Genvia solution after different reaction time frames:

Time	Dilution of Genvia and corresponding OD values							
	N	1:1	1:2	1:5	1:10	*Povsitive Reference	**Negative Reference	Positive serum without treatment
1 minute	0.144	0.179	0.193	0.424	0.618	1.256	0.068	0.841
2 minutes	0.113	0.122	0.178	0.324	0.604	1.256	0.068	0.841
5 minutes	0.091	0.104	0.165	0.215	0.611	1.256	0.068	0.841
10 minutes	0.072	0.101	0.142	0.154	0.552	1.256	0.068	0.841
15 minutes	0.069	0.083	0.129	0.136	0.492	1.256	0.068	0.841

[The actual final dilution ratios of Genvia to HBsAg positive serum are 1:10, 1:20, 1:30, 1:50, and 1:100 respectively.]

[* Purified HBsAg is included in test kit as positive reference.]

[** Negative reference is the blank wells on reaction micro-titer plate.]

5. P/N values of 30 samples treated by Genvia solution of different dilutions after different reaction time (P/N value = sample OD reading/negative reference OD reading):

Time	P/N					
	N	1:1*	1:2	1:5	1:10	Serum without treatment
1 minute	2.12	2.63	2.84	6.24	9.09	12.37
2 minutes	1.66	1.79	2.62	4.76	8.88	12.37
5 minutes	1.34	1.53	2.43	3.16	8.99	12.37
10 minutes	1.06	1.49	2.09	2.26	8.12	12.37

6. The percentage of OD value of positive serum treated by Genvia solution comparing to OD value of untreated positive serum:

Time	%*				
	N	1:1	1:2	1:5	1:10
1 minute	9.8	14.4	16.2	46.1	71.2
2 minutes	5.8	7.0	14.2	33.1	69.3
5 minutes	2.9	4.6	12.5	19.0	70.2
10 minutes	0.5	4.3	9.6	11.1	62.6
15 minutes	0.1	1.9	7.9	8.8	54.9

$$[* \% = \frac{\text{Sample's OD Value - Negative Reference OD Value}}{\text{Positive Serum OD Value - Negative Reference OD Value}}$$

B. Analysis and Conclusion

When mixing different dilutions of Genvia solution with HBsAg positive serum, Genvia has clearly effect on all of the final OD value readings. The result of this test shows surely that Genvia has evidently destroying effect on HBsAg of Hepatitis B patient serum. In serum, there are many of co-existing organic materials such as other proteins to intervene the reaction and make it much harder for any disinfectant to destroy/damage HBsAg. But still, when reaction time reached two minutes, P/N ratio is less than 2.1(The actual dilutions are 1:11, 1:21). Analyzing all of other final P/N values, all of them have smaller P/N values comparing to the untreated HBsAg positive serum. After adding original Genvia solution and 1:1 diluted Genvia solution for 2 minutes, P/N values are less than 2.1.

Test Conducted by: Signature: Seal:

孙健

Annexure M

The Effectiveness of Genvia® Topical Composition on Damaging HAAg

Test conducted by:
Clinical Laboratory Department,
Gu-Lou Hospital
Affiliated to Medical College of Nanjing University
On January 6, 2000

THE EFFECTIVENESS OF GENVIA ON DAMAGING HAAg

January 6, 2000

A. Materials and Method:

1. **Sample**: Two (2) individual fresh feces are collected from most recently diagnosed Hepatitis A patients (acute stage). Patients are diagnosed by clinical symptoms and confirmed by clinical immunology. Samples are kept at 37 degree centigrade and transported to lab. within one hour.

2. **Test Method and Test Kit**: Hepatitis A virus EIA diagnosing kit (See attached copy of instruction sheet of manufacturer), produced according to the standard of Ministry of Public Health of China, by Nanjing Military Medicine Research Institute cooperated with Nanjing Hua-shing Medical Biological Engineering Co. Ltd. Certificate Code: (91) We-Yao-Zun-Zi (Nin-Jun) S-06. Product Batch Code: 991009. The test is conducted strictly under the conditions and steps in accordance with the instruction stated in the test kit.

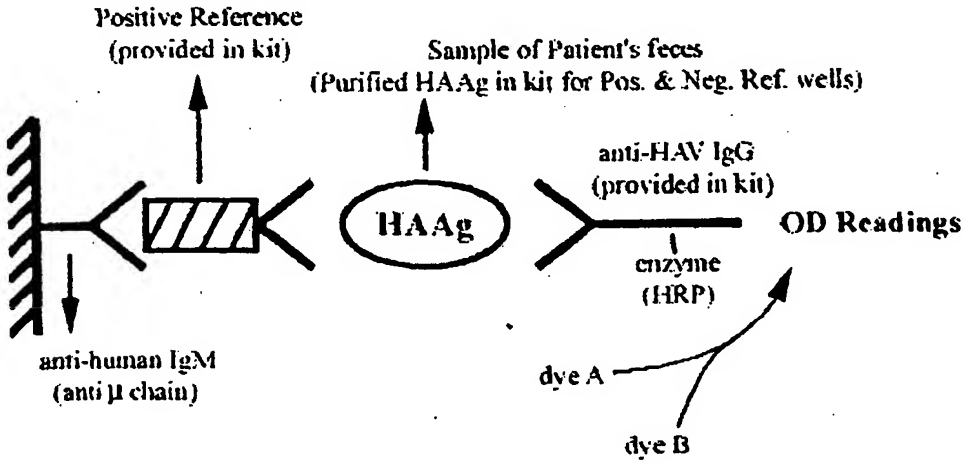
EIA OD Machine in the Test: BIO-RAD Model 550.

2. Object in the Test:

1). Determine the effectiveness of Genvia on destroying Hepatitis A virus (HAAg). Batch code: 99.12.24

3.**Mechanism**:

which the anti-human IgM (anti μ – chain of IgM) has been fixed onto it. Add purified standard Hepatitis A IgM positive serum (provided in the test kit) onto wells of the plate, then add feces sample onto each well with different dilutions of Genvia solutions.



How to determine the test is correctly established: (See the attached instruction sheet.) If the difference of OD values between positive reference provided in test kit and negative reference is large than 0.400, it indicates that the test is correctly established.

Standard of evaluating effectiveness of Genvia on Destroying HAAg: (See the attached instruction sheet.) If OD value of feces sample over negative reference is larger than or equal to 2.1, it is Hepatitis A virus positive. If it is less than 2.1, it is negative. (See attached instruction sheet of test kit). After treatment of Genvia (mix with feces samples by

different dilutions and react for different times) on the wells, if the OD values of feces sample over negative reference is smaller than or equal to 2.1, it indicates Genvia is successfully destroyed HAV (HAAg). Read each well at OD_{450}.

5. Test Procedure

1). Add Patient's feces about the size of a penny into sterilized centrifuge tube. Add 4 - 5ml of 0.9% sterilized NaCl solution into the tube and stir the mixture in tube evenly. After 5 minutes, centrifuge the mixture at the speed of 2,000 turns/minute for 3 minutes. Keep the top portion of solution for test.

2). Within one hour prior to the test, dilute Genvia with sterilized 0.9% NaCl in ratios of 1:1, 1:2, 1:5, 1:10.

3). Add the above-mentioned diluted Genvia solution respectively into HAV feces solution evenly, the mixing ratio of Genvia solution: HAV feces solution is equal to 1:10. Add the mixture as sample onto each well according to different reaction time frames required, and follow each step given in instruction sheet.

4). Set standard positive reference: Add standard purified IgM positive serum and purified HAAg (in accordance with the instruction in test kit), without treatment of Genvia. Negative reference: add standard purified IgM positive serum and wash solution to instead of HAAg. Blank reference: (in accordance with the instruction in test kit).

solution after different reaction time frames:

Table One: Patient No. 1

Reaction Time	Dilutions*				
	N	1:1	1:2	1:5	1:10
1 minute	0.099	0.200	0.283	0.574	0.666
2 minutes	0.094	0.105	0.201	0.400	0.606
5 minutes	0.066	0.087	0.106	0.306	0.591
10 minutes	0.066	0.076	0.085	0.298	0.573
15 minutes	0.061	0.068	0.081	0.284	0.566

[* Actual final dilutions after mix with sample are 1:10, 1:20, 1:30, 1:50, 1:100]

Reference Readings:

Blank: 0.001

Negative Reference: 0.060

* Positive Reference: 0.866

** Positive Reference: 1.305

[* The OD reading is form patient's feces sample without treatment of Genvia. Prepared as described as above.]

[** The OD reading is from purified positive reference provided in test kit.]

Table Two: Patient No. 2

Reaction Time	Dilutions				
	N	1:1	1:2	1:5	1:10
1 minute	0.097	0.196	0.270	0.459	0.601
2 minutes	0.095	0.117	0.260	0.440	0.504
5 minutes	0.069	0.105	0.114	0.401	0.478
10 minutes	0.068	0.100	0.109	0.302	0.408
15 minutes	0.064	0.090	0.104	0.287	0.341

[* Actual final dilutions after mix with sample are 1:10, 1:20, 1:30, 1:50, 1:100]

Reference Readings:

Blank reading: 0.001

Negative Reference: 0.060

* Positive Reference: 0.782

** Positive Reference: 1.305

[* The OD reading is form patient's feces sample without adding HAAg. Prepared as described as above.]

[** The OD reading is from purified positive reference provided in test kit without treatment of Genvia.]

C. Analysis:

The test result shows that Genvia, under different dilution condition and mixed with Hepatitis A virus positive human feces, has reliable effect on the different levels on all final OD values. When Genvia is not diluted or 1:1 diluted and reacts for one (1) minute (one minute is the shortest possible reaction time can be handled and recorded by lab technician.), the change of OD values is significant. The OD reading ratio of sample treated by non-diluted Genvia over negative reference is 1.65, at the first minute. According to the result evaluation standard described in instruction sheet ("If OD value of sample over negative reference is larger than or equal to 2.1, it is Hepatitis A virus positive. If it is less than 2.1, it is negative."), the result of this test proves that Genvia has evidently fact-acting, destroying effect on HAAg.

Test conducted by: Dr. Sun Jian Signature: Seal:

孙健

Annexure N

The Effectiveness of Genvia® Topical Composition on Killing Human Sperm

Test conducted by:
Clinical Laboratory Department,
Gu-Lou Hospital
Affiliated to Medical College of Nanjing University
On December 27, 1999

THE EFFECTIVENESS OF GENVIA ON KILLING HUMAN SPERM

Date: December 27 1999

1. Method and Materials:

1). Sample: Fifty (50) human sperm samples are screened from outpatients at Gu-Lou Hospital. Thirty (30) of the samples are selected as normal human sperm samples, determined by the observation of percentage of normal shape, good mobility and the above-average living rate (in percentage). In this test, all of the samples are fresh human sperms collected within one hour. (See names in Attachment)

2). Object in Test: Genvia. Batch code: 99.12.24. Diluted with sterilized 0.9% NaCl within two hours prior to the test. The dilution ratios are: 1:1, 1:2, 1:5, 1:10, 1:50.

2. Method:

1). Ask each of test recipients to leave sperm in a sterilized, dry test tube. There is no pyocytes and RBCs found in each sample under microscope observation. All of tests of each sample are finished within 30 minutes at room temperature. Each sample, which its living rate is more than 65% in average, is selected.

2). Transfer the selected sperm sample from glass tube onto a sterilized glass plate, 0.1ml on each plate. Observe the plate under microscope and record the living rate of the sperm before test. Add 0.05 - 0.1ml Genvia

sample. Observe the survived living rate, mobility changes and morphological changes of the sperms under microscope at 5 seconds, 15 seconds, 30 seconds, 1 minute, 5 minutes and 10 minutes respectively.

3. Test Results are summarized in the following table:

Time	Surviving rate (%) of sperm after adding Genvia of different dilution				
	N	1:1	1:2	1:5	1:10
5 seconds	0	0.21	0.71	2.05	6.25
15 seconds	0	0	0.18	0.88	2.55
30 seconds	0	0	0	0.12	1.25
1 minutes	0*	0	0	0	0.65
5 minutes	0*	0*	0	0	0.12
10 minutes	0*	0*	0	0	0

Notice:

1). The living rates of sperm in this table are mean values of 30 tested samples, comparing to the living rates before test.

2). We observed ten (10) locations randomly for each sample at each dilution, on the same smear plate. If one sperm having mobility is seen under microscope, the surviving rate is recorded as 0.5%, then divided by average mean of living rate before test.

3). The asterisk in the table indicates that more than 80% sperms are dissolved and disappeared from observation areas. And, it is more than half of the sample treated and observed by the same Genvia solution repeatedly.

4. Conclusion:

Non-diluted Genvia solution kills sperms instantly. 1:1 diluted Genvia kill sperms in 15 seconds. 1:2 diluted Genvia kill sperms in 30 seconds.

Test Conducted by: Dr. Sun Jian Signature 孙健 Seal 孙健

Annexure O

List of the Patients

Provided by:
Clinical Laboratory Department,
Gu-Lou Hospital
Affiliated to Medical College of Nanjing University

Attachment

A. List of 30 patients whose sperm is used in the test: Sun Hz-Bin, Shi Yew-You, Sun Xin-Zhong, Ni Dong-Liang, Wu Kai-De, Liu Bin, Chen Tong-Fu, Li Bao-Sheng, Ma Yuan-Tao, Guo Kui, Wang Biao-Hui, Zhang Fu-Rong, Guo Qing-Li, Gai Jun-Ping, Liu Si-Xian, Zhang Sheng-Bin, Ge Jian-Liang, Mao Hong-Tao, Wang Hong-Jun, Huang Ming-Yu, Ye De-Qin, Chen Wei-Tie, Liu Jian-Wu, Wang Fu-Cai, Qian Da-Jun, Liang Jun-Gang, Zhou Jie, Ding Cheng-Yong, Li Jian-Duan, Li Hong-Ping

B. List of trichomoniasis patients: Liu Chun-Hua, Zhang A'Mei, Chen Mei-Feng

C. List of gonorrhea patients: Zhao Dong-Ke, Yao Jun-Biao, Shao Ming-Yun

D. Microscopic photos of gonorrhea test

Test Conducted by Dr. Sun Jian/Director of

Clinical laboratory of biochemistry & virology

Gu-Lou Hospital

Affiliated with School of Medicine

Nanjing University, Nanjing P. R. China

Signature: 孙健 Seal:

Annexure P

Activity of Genvia® Topical Composition to Reverse Transcriptase of HIV-1

Test conducted by:
National Center for STD and Leprosy Control,
Institute of Dermatology
Chinese Academy of Medical Science
On 2000/03/08

药物 Genvia 对艾滋病毒 1 型逆转录酶（HIV-1 RT）的灭活作用

中国医学科学院 中国协和医科大学

医药生物技术研究所

2000 年 3 月 8 日

药物 Genvia 对艾滋病毒 1 型逆转录酶（HIV-1 RT）的灭活作用

中国医学科学院 中国协和医科大学 医药生物技术研究所

1 目的：

中国医学科学院南京皮肤病研究所制备的消毒剂 Genvia 有灭活支原体作用，本方法观察其对 HIV-1 逆转录酶的灭活作用。

2 材料和方法

2.1 药物 Genvia，为棕红色液体，由南京皮肤病研究所提供，膦甲酸钠（PFA）(批号：921010) 由常州一厂制备作为对照药。

2.2 试剂: poly(A)$(dT)_{15}$ 为 Boehringer Mannheim GmbH 公司产品；^{3}HdTTP 为杜邦公司产品；DTT，牛血清白蛋白为天象人公司产品。其余均为国产分析纯产品。

2.3 HIV-1 逆转录酶 P66/P51: 本室自己制备并纯化，质粒（PKTR2）来自美国。

2.4 方法:

2.4.1 将样品用双蒸水稀释成 1：10，1：20，1：40，1：80，1：160，1：320，1：640，1：1280，1：2560 ，8 个不同浓度。

2.4.2 20ul 酶样品与 20ul 不同浓度药液混合，37°C 分别作用 30 秒，1 分钟，5 分钟。同时设酶对照及空白对照。

2.4.3 分别在每管中加入 20ul 酶反应底物缓冲液，37°C 反应半小时。

2.4.4 O°C 水浴终止反应。

2.4.5 点样于滤纸片上，冷 5%三氯乙酸洗 3 次。

2.4.6 95%乙醇脱水。

2.4.7 80°C 烤干，将滤纸片置于闪烁液中，测放射性强度 CPM。

2.5 半数有效浓度（IC_{50}）计算公式

$$IC_{50}=\text{Antilg}\left(\log(\text{<50\%药物浓度}) + \frac{\text{50-<50\%累积抑制率}}{\text{>50\%累积抑制率-<50\%累积抑制率}} \times \log(\text{稀释倍数})\right)$$

3 结果 ：

表 1 药物对 HIV-1 RT 的抑制作用 IC_{50} （稀释度）

时间	IC_{50}		
	第一批(2000，1，17)	第二批(2000,01，21)	两批平均(X±SD)
30 秒	1/138	1/222	1/171± 0.002
1 分钟	1/260	1/454	1/327±0.0012
5 分钟	〈1/2560	〈1/2560	〈1/2560±0.00
PFA	0.045ug/ml	0.044ug/ml	0.0445±0.00071 ug/ml

时，对 HIV-1 逆转录酶直接灭活的半数有效稀释度（IC_{50}）为 1/171± 0.002，1 分钟 IC_{50} 为 1/327± 0.0012，5 分钟时 IC_{50} 小于 1/2560± 0.00。

设计、指导、审核：陈鸿珊 研究员 陈鸿珊 1999.12.28

实验、计算、打印：陈湘红 助理研究员 郭志敏 博士生

原始记录保存处：中国医学科学院 中国协和医科大学 医药生物技术研究所病毒室

联系人：郭志敏 博士生

INSTITUTE OF DERMATOLOGY
CHINESE ACADEMY OF MEDICAL SCIENCES

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THE ACTIVITY OF Genvia™ TO REVERSE TRANSCRIPTASE OF HUMAN IMMUNODEFICIENCY VIRUS-1

1 Objective

To test the activity of Genvia™ to reverse transcriptase of human immunodeficiency virus -1 (HIV-1 RT).

2 Materials and Methods

2.1 Genvia™, a liquid with brown color. Foscarnet sodium (Lot No 921010), manufactured by Changzhou Pharm Co, China, was used as control.

2.2 Reagents: poly(A)$(dT)_{15}$ (Boehringer Mannheim GmbH), ^{3}HdTTP (Doupont), DTT, bovine albumin (home-made).

2.3 HIV-1 RT P66/P51, prepared and purified in our lab; Plasmid PKTR2 (USA).

2.4 Methods:

2.4.1 Genvia™ was diluted with double distilled water into following concentrations: 1:10, 1:20, 1:40, 1:80, 1:160, 1:320, 1:640, 1:1280, 1:2560.

2.4.2 20 μ l enzyme and 20 μ l Genvia™ with different concentration was mixed and reacted for 30sec, 1min, 5min in 37℃, respectively. Enzyme control and blank control were included in the test.

2.4.3 20 μ l substrate was added to each test tube and put in 37℃ for 30min.

2.4.4 The reaction was stopped in 0℃

2.4.5 The reaction dilution was applied to filter stripe and washed with cold acetocaustin.

2.4.6 Dehydrated with 95% alcohol.

2.4.7 The stripe was dryed in 80℃ and put in scintillation liquid. The radiation intensity (CPM) was measured.

2.5 IC_{50} was calculated:

IC_{50}= Antilg [log<50%dilution+(50-<50%cumulate inhibition rate / (>50% cumulate inhibition rate-<50% cumulate inhibition rate))×log dilution titre]

3 Results

Table 1. The inhibition IC_{50} of Genvia™ to HIV-1 RT

Time	IC_{50}		
	1st run(00-1-17)	2nd run(00-1-21)	Mean(x±SD)
30sec	1/138	1/222	1/171±0.002
1min	1/260	1/454	1/327±0.0012
5min	<1/2560	<1/2560	<1/2560±0.00
Foscarnet	0.045 μ g/ml	0.044 μ g/ml	0.0445±0.00071 μ l/ml

4 Conclusion

The results suggest that Genvia™ have a direct inhibition effect on HIV-1 RT in vitro. The longer it reacts with HIV-1 RT, the stronger it exert inhibition. The IC_{50} of Genvia™ are 1/171 ±0.002 in 30sec, 1/327±0.0012, 1/2560±0.00, respectively.

Technicians: Chen Shanhong, Guo Zhiming
Supervisor: Chen Hongshan

Annexure Q

Activity of Genvia® Topical Composition for In vitro bactericidal effects on Neisseria Gonorrhoeae

Test conducted by:
National Center for STD and Leprosy Control,
Institute of Dermatology
Chinese Academy of Medical Science
On August 26, 1999

检 测 报 告

一、待检样品

Genvia™ 消毒液，（批号：990720），来自美国 Evans-Carter International Inc.。

二、材料与方法

1.淋球菌菌株 WHO 国际标准菌株。

2. Genvia™ 消毒液为棕色液体。用灭菌双蒸水稀释，分别配制成不同稀释度的水溶液。

3.试验方法 按卫生部"消毒剂鉴定技术规范"，结合淋球菌特点稍加改良。稀释后的药液与等体积的菌悬液(1×10^8 CFU/ml)混合，于 37℃分别作用 15 秒、30 秒、1 分、2 分、5 分钟。用特制接种环取一满环混合物接种于 GC 血液琼脂培养基上,35℃烛缸培养 36 小时后观察结果。

三、结果 结果见附表

附表 Genvia™ 消毒液对淋球菌的杀菌作用

菌株	作用时间	稀释浓度 1:2	1:5	1:10	1:50	1:100	1:500	空白对照
WHO 标准株	15 秒	-	-	-	-	-	+ + + +	+ + + +
	30 秒	-	-	-	-	-	+ + + +	+ + + +
	1 分	-	-	-	-	-	+ + + +	+ + + +
	2 分	-	-	-	-	-	+ + + +	+ + + +
	5 分	-	-	-	-	-	+ + + +	+ + + +

注：- 平皿划线处无菌生长。

\+ 淋球菌生长菌落数在 10 个以内。

++ 淋球菌生长菌落数在 10－100 个。

+++ 淋球菌生长菌落数在数百个,但未融合成片。

++++ 淋球菌生长菌落数融合成片,无法计数。

四、结论

检测结果表明, Genvia™ 消毒液 1：100 稀释时，作用 15 秒能杀死淋球菌。

检 测 人：尹跃平 戴秀芹

中国医学科学院皮肤病研究所

全国性病麻风病控制中心

一九九九年四月二十六日

IN VITRO BACTERICIDAL EFFECTS OF GENVIA™ ON *NEISSERIA GONORRHOEAE*

1. Sample

GENVIA™, Evans-carter, International Inc, Batch number: 990720.

2. Material and method

① Strain: Standard Strain of *Neisseria gonorrhoeae*

② Method: "Technical Standards for Evaluation of Disinfectants" issued by the Ministry of Public was modified based on the characteristics of *Neisseria gonorrhoeae.*

3. Result

The results of effects of GENVIA™ on *Neisseria gonorrhoeae* are as following.

BACTERICIDAL EFFECTS OF GENVIA™ ON *NEISSERIA GONORRHOEAE*

Strain	Time	Dilution						Control
		1:2	1:5	1:10	1:50	1:100	1:500	
Neisseria gonorrhoeae (WHO Standard Strain)	15"	–	–	–	–	–	+	+
	30"	–	–	–	–	–	+	+
	1'	–	–	–	–	–	+	+
	2'	–	–	–	–	–	+	+
	5'	–	–	–	–	–	+	+

4. Conclusion

The results show that GENVIA™ has bactericidal effects on *Neisseria gonorrhoeae* at 1:100 dilution in 15 seconds.

Reporter: Yin Yue-ping (尹跃平)、 Dai Xiu-qin (戴秀芹)

Institute of Dermatology,
Chinese Academy of Medical Science
National Center for STD and Leprosy Control
August 26, 1999

Annexure R

Activity of Genvia® Topical Composition for In vitro bactericidal effects on Mycoplasma

Test conducted by:
National Center for STD and Leprosy Control,
Institute of Dermatology
Chinese Academy of Medical Science
On August 26, 1999

GENVIA杀支原体作用
检测报告

一、样品名称、来源及批号:GENVIA.Evans—carter,International Inc.
Batch' 990720

二、实验支原体菌株:解脲支原体(Ureaplasma urealyticum)国际标准株。

三、培养基:解脲支原体液体培养基。

四、实验方法:按卫生部"消毒剂鉴定技术规范",根据支原体特点稍作改良。

五、样品试验浓度:用灭菌蒸馏水将样品稀释成下列浓度:1:2, 1:5、1:10、1:50、1:100、1:500。

六、实验结果(见表)。

作用时间	药物稀释浓度			
	1:2	1:5	1:10	1:50
15秒	-	-	-	+
30秒	-	-	-	+
1分	-	-	-	+
2分	-	-	-	+
5分	-	-	-	+

空白对照:-(无支原体生长)

不加样品对照:+(有支原体生长)

七、结论:检测结果表明,用1:10稀释浓度的GENVIA,作用15秒即可杀灭解脲支原体。

中国医学科学院

本实验负责人:王荷英

检测人员:[illegible]王红春

一九九九年八月二十三日

IN VITRO BACTERICIDAL EFFECTS OF GENVIA™ ON MYCOPLASMA

1. Sample

GENVIA™, Evans-carter, International Inc, Batch Number:990720.

2. Material and method

① Strain: Standard Strain of *Ureaplasma urealyticum*

② Method: "Technical Standards for Evaluation of Disinfectants" issued by the Ministry of Public was modified based on the characteristics of mycoplasmas.

3. Result

The results of effects of GENVIA™ on *Ureaplasma urealyticum* are as following.

BACTERICIDAL EFFECTS OF GENVIA™ ON MYCOPLASMA

Strain	Time	Dilution				Control
		1:2	1:5	1:10	1:50	
Ureaplasma urealyticum	15"	-	-	-	+	+
	30"	-	-	-	+	+
	1'	-	-	-	+	+
	2'	-	-	-	+	+
	5'	-	-	-	+	+

4. Conclusion

The results show that GENVIA™ has bactericidal effects on *Ureaplasma urealyticum* at 1:10 dilution in 15 seconds.

Reporter: Wang He-ying (王荷英)、 Shi Mei-qin (施美琴)、 Wang hong-chun (王红春)

Institute of Dermatology
Chinese Academy of Medical Science
National Center for STD and Leprosy Control
August 26, 1999

Annexure S

Effect of Immobilization test of Genvia® Topical Composition on Treponema Pallidum in vitro

Test conducted by:
National Center for STD and Leprosy Control,
Institute of Dermatology
Chinese Academy of Medical Science
On August 4, 1999

一、待检样品

Genvia™消毒液(批号:990720)，来自美国Evans－Carter International,Inc公司。

二、材料与方法

1.梅毒螺旋体菌株(Nichols strain)。

2.Genvia™消毒液为棕色液体。用无菌蒸馏水稀释，分别稀释成不同浓度的液体。

3.试验方法 按梅毒螺旋体制动试验，于25～30℃，稀释液与梅毒螺旋体混合，作用1分钟、2分钟、4分钟、8分钟，在暗视野显微镜下观察结果。

4.结果(见表)

菌株	作用时间	稀释浓度 1:2	1:5	1:10	1:20
Nichols	1分	－	+	+	
	2分	－	－	+	+
	4分	－	－	－	+
	8分	－	－	－	+

结果判断:有制动作用(－)、无制动作用(+)

四、小结

检测结果表明，Genvia™消毒液1:2作用1分钟，1:5作用2分钟，1:10作用4分钟可制动梅毒螺旋体。

检测人:龚匡隆 尤永燕

中国医学科学院皮肤病研究所
1999年8月14日

ON TREPONEMA PALLIDA IN VITRO

1. Sample

GENVIA™, Evans-carter, International Inc. Batch #: 990720.

2. Material and method

(1) Strain: Treponema pallidum subsp. Nichols strain.

(2) Method: T. pallidum immobilization test.

3. Result

The results of effects of GENVIA™ on T. pallidum are as following.

EFFECTS OF IMMOBILIZATION TEST OF GENVIA™ ON T. PALLIDUM

Strain	Time (min)	Dilution 1:2	1:5	1:10	1:20
T. pallidum Nichols	1	−	+	+	
	2	−	−	+	+
	4	−	−	−	+
	8	−	−	−	+

Results criterion: Immobilization effects (−)

Non-immobilization effects (+)

4. Conclusion

The test results show that GENVIA™ had immobilization effects on T. pallidum at 1:2 dilution in 1 minute, 1:5 dulition in 2 minute and 1:10 dulition in 4 minute.

Reporter: Gong kuang-long You Yong-yan

Insitute of Dermatology,
Chinese Academy of Medical Science
August 4, 1999

Annexure T

In vitro Bactericidal Effects of Genvia® Topical Composition on Chlamydia Trachomatis

Test conducted by:
National Center for STD and Leprosy Control,
Institute of Dermatology
Chinese Academy of Medical Science
On August 26, 1999

一、材料与方法

1. 沙眼衣原体菌株　沙眼衣原体L3型，国际标准菌株。

2. Genvia（批号990720）　用pH 7.2 PBS稀释，配制成不同浓度的溶液。

3. 试验方法　按卫生部“消毒剂鉴定技术规范”，结合沙眼衣原体特点加以改良。稀释后的药液与L3株沙眼衣原体作用15秒、30秒、1分钟、2分钟、5分钟后，用稀释法中止反应并接种McCoy单层细胞。离心，换分离培养基，培养48小时后，作碘染色，显微镜下检查包涵体。

二、结果

见表1

表1　Genvia对沙眼衣原体的杀菌作用

菌株	作用时间	药物稀释浓度				无药对照
		1:2	1:5	1:10	1:50	
L3	15秒	−	−	−	+	+
	30秒	−	−	−	+	+
	1分钟	−	−	−	+	+
	2分钟	−	−	−	+	+
	5分钟	−	−	−	+	+

\+　见到细胞内衣原体的包涵体

−　无包涵体

三、结论

Genvia 1:10稀释时，作用15秒对沙眼衣原体有杀灭作用。

检测人：王千秋，钟铭英

中国医学科学院皮肤病研究所

全国性病艾滋病控制中心

一九九九年八月二十六日

IN VITRO BACTERICIDAL EFFECTS OF GENVIA ON *CHLAMYDIA TRACHOMATIS*

1 Sample tested

Disinfectant: GENVIA™, Evans-Carter International, Inc, Batch Number 990720.

2 Materials and Methods

2.1 Strain: L3 strain, a standard strain of *Chlamydia trachomatis.*

2.2 Methods: Technical Standards for Evaluation of Disinfectant issued by the Ministry of Public Health was modified based on the characteristics of *Chlamydia trachomatis.*

3 Results

The results of bactericidal effects of GENVIA™ on *Chlamydia trachomatis* are as following:

The bactericidal effects of GENVIA™ on Chlamydia trachomatis

Strain	Time	Dilution (v/v)				Control
		1:2	1:5	1:10	1:50	
Chlamydia trachomatis (L3 strain)	15 sec	−	−	−	+	+
	30 sec	−	−	−	+	+
	1 min	−	−	−	+	+
	2 min	−	−	−	+	+
	5 min	−	−	−	+	+

−: without chlamydial growth; +: with chlamydial growth

4 Conclusion

The results show that GENVIA™ has bactericidal effects on *Chlamydia trachomatis* at 1:10 dilution in 15 seconds.

Reporter: Wang Qianqiu (王千秋), Zhong Mingying (钟铭英)

中国医学科学院

Institute of Dermatology
Chinese Academy of Medical Sciences
National Center for STDs and Leprosy Control

August 26, 1999

Annexure U

In vitro bactericidal effects of Genvia® Topical Composition on Trichomonas Vaginalis

Test conducted by:
National Center for STD and Leprosy Control,
Institute of Dermatology
Chinese Academy of Medical Science
On January 26, 2000

Genvia 消毒液对阴道毛滴虫的杀虫作用
检 测 报 告

一、 待检样品：

Genvia™消毒液，（批号：990720），来自美国 Evans-Carter International Inc.。

二、材料与方法：

*1.*实验虫株：阴道毛滴虫。

2. Genvia™消毒液为棕色液体。用灭菌蒸溜水稀释，分别配成不同稀释度的水溶液。

*3.*试验方法：按卫生部“消毒剂鉴定技术规范”，结合阴道毛滴虫的特点稍加改良。滴虫接种量为 $0.5 X10^5 cfu/ml$。作用时间分别为 15 秒、30 秒、1 分、2 分、5 分钟后用稀 释 法 中止反应。离心后将滴虫接种于肝浸液培养基中，*37*℃培养 *48* 小时后观察结果。

三、结果：结果见附表。

附表：Genvia™消毒液对阴道毛滴虫的杀虫作用

时 间	稀释浓度 (v/v)						空白对照
	1:2	1:5	1:10	1:50	!:100	1:500	
15 秒	—	±	±	±	+	+	+
30 秒	—	±	±	±	+	+	+
1 分钟	—	±	±	±	±	+	+
2 分钟	—	±	±	±	±	+	+
5 分钟	—	±	±	±	±	+	+

(—):可见虫体破残碎片和无活动虫体;

(±):无活动虫体但虫体完整;

(+):有活动虫体。

四、结论：

检测结果表明：Genvia™消毒液 *1:2* 稀释时，作用 *15* 秒可对人阴道毛滴虫产生杀灭作用；在 *1:100* 稀释时作用 *1* 分钟，可对人阴道毛滴虫产生抑制作用。

检测人：余艳华

中国医学科学院皮肤病研究所
全国性病麻风病控制中心
二 000年一月二十六日

IN VITRO BACTERICIDAL EFFECTS OF GENVIA™ ON *TRICHOMONAS VAGINALIS*

1. Sample

GENVIA™, Evans-carter, International Inc, Batch #990720.

2. Material and method

① Strain: Clinical strain of *Trichomonas vaginalis*.

② Method: "Technical Standards for Evaluation of Disinfectants" issued by the Ministry of Public was modified based on the characteristics of *Trichomonas vaginalis*. Inoculation amount is 0.5 X 10^5/ml, reaction time is 15 seconds, 30 seconds 1min, 2min and 5min. Incubate in liver suspension solution incubate at 37°C for 48hrs.

3. Result

The results of effects of GENVIA™ on *Trichomonas vaginalis* are as following.

BACTERICIDAL EFFECTS OF GENVIA™ ON *TRICHOMONAS VAGINALIS*

Strain	Time	Dilution						Control
		1:2	1:5	1:10	1:50	1:100	1:500	
Trichomonas vaginalis	15"	–	±	±	±	+	+	+
	30"	–	±	±	±	+	+	+
	1'	–	±	±	±	±	+	+
	2'	–	±	±	±	±	+	+
	5'	–	±	±	±	±	+	+

(-): No complete body of *Trichomonas vaginalis;*

(±) No active *Trichomonas vaginalis* but have complete body

(+): Active *Trichomonas vaginalis*;

4. Conclusion

The results show that GENVIA™ has bactericidal effects on *Trichomonas vaginalis* at 1:2 dilution in 15 seconds, and bacterial inhibited at 1:100 dilution in 1 minutes.

Reporter: Yu Yan-hua (余艳华)

Institute of Dermatology,
Chinese Academy of Medical Science
National Center for STD and Leprosy Control
Jan 26, 2000

Annexure V

In vitro inhibition of HIV Reverse Transcriptase by Genvia® Topical Composition

Test conducted by:
National Center for STD and Leprosy Control,
Institute of Dermatology
Chinese Academy of Medical Science
On January 31, 2000

Genvia 体外逆转录酶抑制试验

检测报告

一、待检样品：

美国 Evans-Carter International Inc.提供 Genvia 消毒液，（批号：990720）。

二、材料：

1. HIV-RT
2. H^3-TTP
3. poly（A）.（dT）15

三、方法：

1. 样品稀释
2. 稀释后的样品与逆转录酶混合后，加入体外转录反应体系。
3. 反应产物测试 CPM。

四、结果：

待检样品 1：120 稀释，作用 30 秒钟对 HIV-RT 有抑制作用。

五、结论：

1：120 稀释的 Genvia 消毒液作用 30 秒钟对 HIV-RT 有抑制作用，建议进一步作 HIV 抑制试验。

中国医学科学院皮肤病研究所

2000年1月[illegible]日

皮肤病研究所

Test Report (Simplified)

In Vitro Inhibition of HIV Reverse Transcriptase by Genvia

1). Sample: Geniva, a disinfectant product, produced and presented by Evans-Carter International, Inc. Batch number: 990720

2). Main Testing Materials:

a). HIV Reverse Transcriptase (HIV-RT)
b). H^3 – TTP
c). Poly (A) (dT)15

3). Method:

a). Dilute Genvia into a series of diluted solutions.
b). Follow the protocol. Mix diluted Genvia solution with HIV-RT, add into HIV-RT reaction system.
c). Detect the level of CPM in reaction product.

4). Test Result:

When original Genvia solution diluted up to 1:120, it still has inactivation effect on HIV-RT, at reaction time of 30 seconds.

5). Conclusion:

When original Genvia solution diluted up to 1:120, it still has inactivation effect on HIV-RT, at reaction time of 30 seconds.

Institute of Dermatology
Chinese Academy of Medical Science
National Center for STD and Leprosy Control
January 31, 2000

中国医学科学院 皮肤病研究所

Annexure W

In vitro Inactive Effect of Genvia® Topical Composition on Herpes Simplex Virus Type 2

Test conducted by:
National Center for STD and Leprosy Control,
Institute of Dermatology
Chinese Academy of Medical Science
On August 19, 1999

一、材料与方法

1. 单纯疱疹病毒毒株　单纯疱疹病毒Ⅱ型(HSV-2)333株,国际标准毒株。

2. Genvia™ 消毒液（批号 990720）　来自美国 Evans-Carter International, Inc. 公司。用PBS(pH 7.2)稀释,配制成不同浓度的溶液。

3. 试验方法　按卫生部“消毒剂鉴定技术规范”,结合单纯疱疹病毒的特点加以改良。稀释后的药液与HSV-2 333株作用15秒、30秒、1分、2分、5分钟后,用稀释法中止反应并接种于Vero细胞单层。孵育2小时，换维持培养基，培养72小时后，在显微镜下观察单纯疱疹病毒的特征性细胞病变(CPE)，以此判断有无病毒生长。

二、结果

见表1

表1　Genvia™消毒液对单纯疱疹病毒Ⅱ型(HSV-2)的灭活作用

毒株	作用时间	药物稀释浓度(v/v)					无药对照
		1:2	1:5	1:10	1:50	1:100	
HSV-2 333株	15秒	−	−	−	−	+	+
	30秒	−	−	−	−	+	+
	1分	−	−	−	−	+	+
	2分	−	−	−	−	+	+
	5分	−	−	−	−	+	+

−　无细胞病变(CPE)　　+　有CPE

三、结论

Genvia™消毒液1:50稀释时，作用15秒钟对单纯疱疹病毒Ⅱ型有灭活作用。

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全国性病麻风病控制中心

一九九九年八月十九日

IN VITRO INACTIVE EFFECTS OF GENVIA™ ON HERPES SIMPLEX VIRUS TYPE 2

1. Sample tested

Disinfectant: GENVIA™, Evans-Carter International Inc, Batch Number: 990720.

2. Material and Methods

①Strain: Herpes simplex virus type 2 (HSV-2) 333 strain, one of the international standard strains of herpes simplex virus type 2.

②Methods: "Technical Standards for Evaluation of Disinfectants" issued by the Ministry of Public Health was modified based on the characteristics of herpes simplex virus.

3. Results

The results of inactive effects of GENVIA™ on herpes simplex virus are as following.

Inactive effects of GENVIA™ on herpes simplex virus type 2

Strain	Time	Dilution(v/v)					Control
		1:2	1:5	1:10	1:50	1:100	
HSV-2 333 strain	15 seconds	−	−	−	−	+	+
	30 seconds	−	−	−	−	+	+
	1 minute	−	−	−	−	+	+
	2 minutes	−	−	−	−	+	+
	5 minutes	−	−	−	−	+	+

−: without cytopathic effects; +: With cytopathic effects

4. Conclusion

The results show that GENVIA™ has inactive effects on herpes simplex virus type 2 at 1:50 dilution in 15 seconds.

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